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|--|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/589,769   | 08/17/2006    | Ladislav Cvak        | TEVGAL 3.3-020      | 2277             |
| 530  | 7590          | 09/25/2008           | EXAMINER            |                  |
| LERNER, DAVID, LITTENBERG,<br>KRUHMOLZ & MENTLIK<br>600 SOUTH AVENUE WEST<br>WESTFIELD, NJ 07090 |               |                      | MABRY, JOHN         |                  |
| ART UNIT   | PAPER NUMBER  |                      |                     | 1625             |
| MAIL DATE  | DELIVERY MODE |                      |                     |                  |
| 09/25/2008   | PAPER         |                      |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |
|------------------------------|--------------------------------------|------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/589,769 | <b>Applicant(s)</b><br>CVAK ET AL. |
|                              | <b>Examiner</b><br>John Mabry, PhD   | <b>Art Unit</b><br>1625            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11/02/2007.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2-23 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
6) Other: \_\_\_\_\_

***Response to Amendment(s)***

Applicant's response on May 5, 2008 filed in response to the Office Action dated November 2, 2007 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

***35 USC § 112 Rejection(s)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The 112-2<sup>nd</sup> rejection of claims 1-23 regarding the term "extracting" have been overcome in view of Applicants amendment to the claim.

***35 USC § 103(a) Rejection(s)***

Applicant's arguments with respect to 103(a) rejections have been fully considered and are persuasive. The 103(a) rejection of claims 1-23 regarding obviousness over Lek (GB 1,299,557) in view of Keating (Lecture Notes) have been withdrawn.

The rejection of claims 1-23 under 35 U.S.C. 103(a) as unpatentable over Cvak (1999) has been fully considered and is partially persuasive.

Applicant argues that Cvak refers to the use of various organic solvents for the extraction of ergot, namely "methylenechloride, trichloroethylene, ethyl acetate, acetone, methylisobutyl ketone and mixtures of toluene with methanol or ethanol and

ether with ethanol..." and that the reference does not teach or suggest the concentrations of ethanol and/or toluene in such a mixture claimed.

The Examiner maintains the rejection of claims 2-23 under 35 U.S.C. 103(a) as unpatentable over Cvak (1999).

Cvak (1999) teaches that mixtures of toluene with ethanol are used to extract ergot. Cvak does not teach or suggest specific concentrations of ethanol and/or toluene mixtures. However, one of ordinary skill in the art would be motivated to experimentally try varying concentrations of toluene-ethanol in order to optimize the percentage of ergot alkaloid extracted.

Cvak (1999) also suggests that the use percolation technology is used to reach satisfactory yields, using a battery or percolators or some type of a continual extractor (see second full paragraph under *Ergot Extraction*, page 375). Additionally, it is common for an artisan of ordinary skill to perform extractions at ambient temperature.

Further, Examiner clearly argues in Non-Final Action (bottom of page 6 and 7) that a crystallization process would be obvious in view Lek (GB 1,299,557). The case was made that Lek discloses a process for isolating ergot alkaloids, which comprises of extracting ergot with toluene, an organic, water immiscible solvent. The ergot extract was then filtered through alumina then dissolved in ethanol then the toluene-ethanol extract was partially evaporated and ergot alkaloid then crystallized from solution. Excess petroleum ether (hexanes) was then added to aid in the crystallization and then collected (see page 1, lines 40-75).

Additionally, Cvak (1999) discloses that two main separation techniques are used for purification of ergot extracts, one of which is crystallization using both bases and their salts. The term salts implies that a acid-base extraction purification process was employed (see *Purification of Ergot Alkaloids*, page 376).

Claims 2-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cvak (1999) in references mentioned above. The adjustment of particular conventional working conditions (e.g. determining result effective amounts of the ingredients beneficially taught by the cited references), as well as adjustment of reaction temperature, reaction time and use of solvents, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan (*In re Mostovych, Weber, Mitchell and Aulbach*, 144 USPQ 38). Accordingly, these types of modifications would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

#### ***Status of the Claims***

Claims 2-23 are pending and rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/  
Examiner  
Art Unit 1625

/Rita J. Desai/  
Primary Examiner, Art Unit 1625